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Part 1. Overview Information

Participating Organization(s)	Centers for Disease Control and Prevention (CDC)
Components of Participating Organizations	National Institute for Occupational Safety and Health (NIOSH)
Funding Opportunity Title	Extension of the World Trade Center Health Registry (U50)
Mechanism of Support	U50 Research Project Cooperative Agreement
Announcement Type	Reissue of RFA-OH-09-002
Funding Opportunity Announcement (FOA) Number	RFA-OH-12-001
Catalog of Federal	93.262, Occupational Safety and Health Program

Domestics Assistance (CFDA) Number(s)	
Category of Funding Activity	Health
FOA Purpose	The purpose of this program is to extend and expand the World Trade Center Health Registry developed and managed by the New York City Department of Health and Mental Hygiene in a cooperative agreement with CDC. The new project will ensure on-going data collection for victims of the September 11, 2001, terrorist attacks on the World Trade Center. The registry will continue to provide a central, unified database to assess short and long term health effects among persons exposed to the WTC disaster. As noted in the James Zadroga 9/11 Health and Compensation Act of 2010 (Public Law 111-347; see 42 USC 300mm-52), the WTC Program Administrator shall ensure that a registry of such victims is maintained that is at least as comprehensive as the World Trade Center Health Registry maintained under the arrangements in effect as of April 20, 2009, with the New York City Department of Health and Mental Hygiene for the purpose of ensuring ongoing data collection relating to victims of the September 11, 2001, terrorist attacks.

Key Dates

Publication Date	To receive notification of any changes to RFA-OH-12-001, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link An email address is needed for this service.
Letter of Intent Due Date	March 12, 2012
Application Due Date	April 11, 2012 by 5:00 PM U. S. Eastern Time. On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U. S. Eastern Time. **Note:** HHS/CDC grant submission procedures **do not** provide a period of time beyond the application due date to correct any error or warning notices of noncompliance

	with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).
Scientific Merit Review	May 2012
Secondary Review	June 2012
Earliest Start Date	July 1, 2012
Expiration Date	April 17, 2012
Due Dates for E. O. 12372	Executive Order 12372 does not apply to this program.

Required Application Instructions
It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Telecommunications for the Hearing Impaired: TTY 1-888-232-6348.

All application instructions outlined in the SF424 (R&R) Application Guide are to be followed with the following requirements:

- Specific Aims are limited to 1 page.
- Research Strategy, including tables, graphs, figures, diagrams, and charts, is limited to 50 pages. See Table of Page Limits.
- Introduction (required for a resubmission or revision application) is limited to 1 page.

A compatible version of Adobe Reader is required for download. For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at http://www07.grants.gov/contactus/contactus.jsp.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

This program is authorized under the Occupational Safety and Health Act of 1970, Section 20(a) and 21(a) (29 USC 669(a) and 29 USC 670); Federal Mine Safety and Health Act, Section 501(a), 30 USC 951(a); Section 301 of the Public Health Service Act as amended (42 USC 241); Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92; and the James Zadroga 9/11 Health and Compensation Act of 2010 (Public Law 111-347; 42 USC 300mm-300mm-61).

Background

In 2002, the Agency for Toxic Substances and Disease Registry (ATSDR) and the New York City Health Department (NYCHD) established the World Trade Center Health Registry (WTCHR) (http://www.nyc.gov/html/doh/wtc/html/home/home.shtml) with the goal of monitoring the health of people directly exposed to the WTC disaster. This goal included identifying long-term physical and mental health effects of the 9/11 WTC disaster; disseminating findings and recommendations to enrollees and others exposed, the public, and the scientific community; sharing information about 9/11-related resources and services; and informing healthcare policy and disaster response planning.

The Registry has conducted three major health surveys and surveyed responders who worked on (a) recovery, clean-up, or other 9/11 disaster-related activities at the Staten Island Landfill or (b) as barge workers transporting WTC materials to Staten Island Landfill (http://www.nyc.gov/html/doh/wtc/html/registry/survey-materials.shtml). The Registry completed its adult follow-up survey in 2007 and the child survey the following year. In 2011, the Registry launched its third follow-up surveys for adults, adolescents and parents of adolescents (http://www.nyc.gov/html/doh/wtc/html/registry/about.shtml). The results of these surveys will help determine to what extent physical and mental health conditions have persisted, and whether any new symptoms and conditions have emerged. Another important goal is to identify and help address gaps in physical and mental health treatment.

The Registry's 2008, 2009, and 2011 reports include information on the Registry's key activities and accomplishments, as well as details on recent findings about the health consequences of 9/11 (http://www.nyc.gov/html/doh/wtc/html/registry/newsletters.shtml).

Today the Registry is an ongoing collaboration with the National Institute for Occupational Safety and Health. It is the largest post-disaster exposure health registry in US history and includes a diverse cohort of over 71,000 directly affected people who performed 9/11-related rescue/recovery work or lived, worked or attended school in lower Manhattan on 9/11/01.

While the full scope of 9/11-related health problems is unknown, a growing body of evidence suggests that significant health conditions have emerged that are associated with the disaster, in particular for those exposed during the collapse of the towers and those who participated substantially in rescue, recovery, and clean-up operations. The Registry serves as a central, unified database to assess short and long term health effects among persons exposed to the WTC disaster; facilitates identification of potential participants for studies conducted by external researchers; and serves as a valuable tool for the WTC Health Program.

Purpose

The purpose of this announcement is to extend and expand the WTCHR developed and managed by the New York City Department of Health and Mental Hygiene in a cooperative agreement with CDC. The new project will ensure on-going data collection for victims of the September 11, 2001, terrorist attacks on the World Trade Center. The WTCHR will continue to provide a central, unified database to assess short and long term health effects among persons exposed to the WTC disaster.

As noted in the James Zadroga 9/11 Health and Compensation Act of 2010 (Public Law 111-347; 42 USC 300mm-300mm-61), the WTC Program Administrator shall ensure that a registry of such victims is maintained that is at least as comprehensive as the WTCHR maintained under the arrangements in effect as of April 20, 2009, with the New York City Department of Health and Mental Hygiene for the purpose of ensuring ongoing data collection relating to victims of the September 11, 2001, terrorist attacks.

A substantial amount of information about the WTCHR can be found at http://www.nyc.gov/html/doh/wtc/html/registry/about.shtml. Current activities include periodic follow-up surveys, epidemiological analyses, cancer and mortality assessments, validating registry findings, identifying and investigating emerging health conditions, and facilitating independent, collaborative research with qualified researchers. There are also a variety of activities related to registry maintenance, registry outreach, dissemination, quality assurance, quality control, coordination, and collaboration. Given the Zadroga Act mandate, prior commitments to the WTCHR, and the funding available, NIOSH reasonably expects that future WTCHR activities will equal or exceed those currently being conducted.

The program will contribute to the following CDC strategic goal in alignment with an HHS strategic goal: Increase the number of communities that protect and promote health and safety and prevent illness and injury to improve the safety, quality, affordability and accessibility of health care.

Objectives

Specific aims include:

1) Maintain the Registry as a valuable public health resource to allow health professionals to track and investigate possible trends in illness and recovery, and to help create guidelines that can save lives and reduce injuries in future disaster settings;

2) Expand knowledge about the long-term health effects of 9/11 by facilitating medical, public health or emergency preparedness research, or other scientific research relevant to the WTCHP;

3) Conduct community activities to respond to the physical and mental health concerns and specific healthcare needs of enrollees and others exposed to 9/11; and

4) Maintain the 9/11 Treatment Referral Program to help enrollees and others find care for 9/11-related health problems.

See Section VIII, Other Information - Required Federal Citations, for policies related to this announcement.

Section II. Award Information

Funding Instrument	Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.
Application Types Allowed	New, Renewal The OER Glossary and the SF 424 (R&R) Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	NIOSH intends to commit over a four-year period approximately $28M in total costs (direct and indirect) to fund 1 application. An award issued under this FOA is contingent on the availability of funds and the submission of a meritorious application.
Ceiling and Floor of Individual Award Range	The combined budget for direct costs for the four-year project period may not exceed $28M.
Project Period Length	The total project period may not exceed four years. Throughout the project period, CDC's commitment to continuation of awards will be conditional on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and

	the determination that continued funding is in the best interest of the Federal government.

HHS/CDC grants policies as described in the HHS Grants Policy Statement (http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions:

- Public/State-Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions

Nonprofits Other Than Institutions of Higher Education

Nonprofits (Other than Institutions of Higher Education)

For-Profit Organizations

Small Businesses

For-Profit Organizations (Other than Small Businesses)

Governments

State Governments

County Governments

City or Township Governments

Special District Governments

Indian/Native American Tribal Governments (Federally Recognized)

Indian/Native American Tribal Governments (Other than Federally Recognized)

U. S. Territory or Possession

Other

Independent School Districts

Public Housing Authorities/Indian Housing Authorities

Native American tribal organizations (other than federally recognized tribal governments)

Faith-based or Community-based Organizations

Regional Organizations
Bona Fide Agents

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.

Non-domestic (non-U.S.) Entities (Foreign Organizations) are not eligible to apply. Foreign (non-U.S.) components of U. S. Organizations are **not** eligible to apply.

Required Registrations
Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- Central Contractor Registration (CCR) – must maintain current registration in CCR to be renewed annually.
- Grants.gov
- eRA Commons

All Program Directors/Principal Investigators (PD/PIs) must work with their institutional officials to register with the eRA Commons or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization.

All registrations must be successfully completed and active before the application due date. Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

Central Contractor Registration and Universal Identifier Requirements
All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.

Additionally, all applicant organizations must register in the Central Contractor Registry (CCR) and maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. CCR is the

primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the CCR internet site at www.ccr.gov (https://www.bpn.gov/ccr/default.aspx).

If an award is granted, the grantee organization **must** notify potential sub-recipients that **no** organization may receive a sub-award under the grant unless the organization has provided its DUNS number to the grantee organization.

Eligible Individuals (Project Director/Principal Investigator) in Organizations or Institutions

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the PD/PI is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for HHS/CDC/NIOSH support.

More than one PD/PI (i.e., multiple PDs/PIs), may be designated on the application for projects that require a "team science" approach and therefore clearly do not fit the single-PD/PI model. Additional information on the implementation plans and policies and procedures to formally allow more than one PD/PI on individual research projects is available at http://grants.nih.gov/grants/multi_pi the SF 424 (R&R) Application Guide.
When multiple PDs/PIs are proposed, NIOSH requires one PD/PI to be designated as the "Contact" PI, who will be responsible for all communication between the PDs/PIs and the NIOSH, for assembling the application materials outlined below, and for coordinating progress reports for the project. The contact PD/PI must meet all eligibility requirements for PD/PI status in the same way as other PDs/PIs. For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF 424 (R&R) Application Guide. Information for the Contact PD/PI should be entered on the SF424 (R&R) Cover component. All other PDs/PIs should be listed in the Research & Related Senior/Key Person component and assigned the project role of "PD/PI." Please remember that all PDs/PIs must be registered in the eRA Commons prior to application submission. **The Commons ID of each PD/PI must be included in the "Credential" field of the Research & Related Senior/Key Person component. Failure to include this data field will cause the application to be rejected. See** http://grants.nih.gov/grants/ElectronicReceipt/preparing.htm for instructions.

When multiple institutions are involved, one institution must be designated as the prime institution and funding for the other institution(s) must be requested via a subcontract to be administered by the prime institution. When submitting a detailed budget, the prime institution should submit its budget using the Research & Related Budget component. All other institutions should have their individual budgets attached separately to the Research & Related Subaward Budget Attachment(s) Form. See Section 4.8 of the SF424 (R&R) Application Guide for further instruction regarding the use of the sub-award budget form.

2. Cost Sharing

This FOA does not require cost sharing as defined in the current ***HHS Grants Policy Statement.***

3. Other

Additional Information on Eligibility
Number of Applications
Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

As defined in the HHS Grants Policy Statement, applications received in response to the same funding opportunity announcement generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC/NIOSH will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application. In addition, NIOSH will not accept any application that is essentially the same as one previously reviewed. Resubmission applications may be submitted, according to the Policy on Resubmission Applications from the SF 424 (R&R) Application Guide. Such applications must include an Introduction addressing the previous peer review critique (Summary Statement).

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity announcement following the directions provided at Grants.gov.

If the applicant encounters technical difficulties with Grants.gov, the applicant should contact Grants.gov Customer Service. The Grants.gov Contact Center is available 24 hours a day, 7 days a week, with the exception of all Federal Holidays. The Contact Center provides customer service to the applicant community. The extended hours will provide applicants support around the clock, ensuring the best possible customer service is received any time it is needed. You can reach the Grants.gov Support Center at 1-800-518-4726 or by email at support@grants.gov. Submissions sent by email, fax, CD's or thumb drives of applications will not be accepted.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. **Applications that are out of compliance with these instructions may be delayed or not accepted for review.** For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.

Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research.
- Name, address, and telephone number of the PD(s)/PI(s).
- Names of other key personnel.
- Participating institutions.
- Number and title of this funding opportunity.

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIOSH staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by March 12, 2012.

The letter of intent should be sent to:

George Bockosh
CDC/NIOSH/OEP
1600 Clifton Road NE, Mailstop E74
Atlanta, GA 30329-4018
Telephone: 412-352-5181
Email: GBockosh@cdc.gov

Required and Optional Components
A complete application has many components, both required and optional. The forms package associated with this FOA in Grants.gov includes all applicable components for this FOA, required and optional.

PHS 398 Research Plan Component/Attachments (Required)
All instructions in the SF424 (R&R) Application Guide must be followed.

Appendix
Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publically available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide**.** See also http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-018.html.

Page Limitations
All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed. For this FOA, the Research Strategy component of the Research Plan narrative is limited to 50 pages.

Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 100 pages for all appendices.

Format for Attachments
Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff.

CDC require all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide (Part I, Section 2) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000).

Failure to follow these requirements may lead to rejection of the application during agency validation or delay in the review process.

3. Submission Dates and Times
Part 1. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via Grants.gov, the online portal to find and apply for grants across all Federal agencies. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, NIH's electronic system for grants administration.

If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to the local copy of their application and submit again through Grants.gov. **Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.**

Once you can see your application in the Commons, be sure to review it carefully as this is what the reviewer will see. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123).

Information on the submission process is provided in the SF424 (R&R) Application Guide.

Note: HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i. e. error correction window).

The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt, validation or rejection may take two (2) business days.

Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov).

4. Intergovernmental Review (E. O. 12372)
This initiative is not subject to intergovernmental review.

5. Funding Restrictions
All HHS/CDC awards are subject to the terms and conditions, cost principles, and other requirements described in the HHS Grants Policy Statement.

Pre-award costs are allowable only as described in the HHS Grants Policy Statement.

Funds relating to the conduct of human subjects research will be restricted until the appropriate assurances and Institutional Review Board approvals are in place.

6. Other Submission Requirements and Information
Application Submission
Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. PAPER APPLICATIONS WILL NOT BE ACCEPTED.

Applicants must complete all required registrations before the application due date.
Section III. Eligibility Information contains information about registration.
For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically.

Important reminders
All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the Central Contractor Registration (CCR). Additional information may be found in the SF424 (R&R) Application Guide.

Applicants are reminded to enter the approved Federal Wide Assurance (FWA) that the applicant has on file with the Office for Human Research Protections, if available. If the applicant has a FWA number, enter the 8-digit number. Do not enter the FWA before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and

complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of this Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications: http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm or http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review, NIH, and responsiveness by CDC/NIOSH. Applications that are incomplete will not be reviewed.

Other Submission Requirements/Special Instructions
Post Submission Materials
Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-10-115.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the NIOSH mission (http://www.cdc.gov/niosh/about.html), all applications submitted to the NIOSH in support of occupational safety and health research are evaluated for scientific and technical merit through the NIOSH peer review system.

Overall Impact
Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the proposed project to provide a central, unified database to assess short and long term health effects among persons exposed to the WTC disaster; facilitate efficient identification of potential participants for studies conducted by external researchers; and to serve as a sustained, powerful tool for the WTC Health Program and related research field(s) in consideration of the following review criteria and additional review criteria.

Scored Review Criteria
Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each.

Significance
Does the project address important needs or critical barriers to help determine physical and mental health conditions which have persisted, and new symptoms and conditions which have emerged, in people exposed to the 9/11 disaster? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practices be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventive interventions used in the World Trade

Center Health Program (WTCHP), occupational health, or public health? Does the proposed project further develop the concept and usefulness of a WTC Health Registry? Will the proposed project further enhance access of the clinical research science community to WTCHP data resources? What is the potential impact of the project on emergency or disaster preparedness as it relates to occupational health and safety?

Investigator(s)
Are the PD/PIs, collaborators, and other key personnel well suited to the project? Do they have appropriate experience and training? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s), other registries, or the WTC Registry? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise? Are the leadership approach, governance and organizational structure appropriate for the project? Has the PI/PD devoted an adequate amount of time and effort to the project? Is there evidence of past collaborations with the WTC Registry or other registries?

Innovation
Does the application describe how the WTCHR will serve as a unique resource for researchers or practioners? Does the application indicate how the WTCHR will collaborate with other resources to further enhance its utility? Is the proposed project forward-looking with regard to registry practices, approaches or methodologies, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed? Does the PI describe how the enhanced WTC Health Registry will serve as a unique resource for researchers and practioners, and how the Registry will collaborate with other related resources to further enhance its utility? Does the application seek to support public health practice paradigms or approaches?

Approach
Are the overall strategy, methodology, feasibility, and rationale well-reasoned and appropriate to accomplish the specific aims of the project? Does the proposed project timeline include clearly established objectives for which progress will be measured objectively by defined methods? Are potential problems, alternative strategies, and benchmarks for success presented? Are there methods for measuring and maximizing coverage, explaining and calculating outcome rates, or sample building and denominator estimation? Are the analytic plans clear, consistent with the research questions, and appropriate for the study design and data available? If the application is new, does it include a credible "phase in" plan for assuming the responsibilities of the registry? Are collaborative activities between the proposed Registry and other WTCHP components adequately described?

Environment
Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available adequate for the project proposed? Will the project benefit from

unique features of the scientific environment, subject populations, or collaborative arrangements? Does the proposed project further develop the concept and usefulness of a World Trade Center Health Registry? Will the proposed project further enhance access of the clinical science community to WTC Health Program data resources? Does the applicant have an existing WTC Health Registry or other registry? Has the applicant addressed how it will work with the existing registry to maintain, enhance and improve through this new cooperative agreement? For potential collaborations, is the commitment and cooperation of other interested parties adequate as evidenced by letters of support specifying the nature and extent of the involvement?

Outreach
Does the application demonstrate an appropriate plan for community outreach and for interaction with the community? Does the proposal include outreach to enrollees to offer healthcare referrals based on survey data? Does the proposal include ways to help keep enrollees engaged (website, reports, direct communications)? Does the applicant currently have a strong liaison component with the community, State and local governments, and other stakeholders? Does the applicant have adequate experience working with these, or similar, stakeholder groups?

Dissemination Plan
Does the application propose an adequate plan to disseminate results to State and local public health officials, community residents, and other concerned individuals and organizations? Does the applicant have experience effectively disseminating information to the community, State and local governments, and other stakeholders? Does the applicant have adequate experience working with these, or similar, stakeholder groups?

Quality Assurance/Quality Control (QA/QC)
Does the application propose adequate quality assurance/quality control steps for ensuring reliable operation of the WTC Health Registry? Does the applicant have experience with QA/QC activities related to the WTC Health Registry or other registries? Is there a plan to validate registry findings?

Evaluation
Does the application propose adequate evaluation steps? Are measures to assess process and outcomes included? Does the applicant have adequate knowledge and experience with evaluation activities relevant to the WTC Health Registry or other registries?

Review Criteria for Renewal Applications
For renewal applications, the following factors will also be considered: Has the existing Registry made significant contributions to the WTC Health Program as demonstrated by its accomplishments? Is there evidence of progress and achievement since the previous competitive review? Is there evidence of integration and synergy? Are collaborative activities between the existing Registry and other WTCHP components adequately described? Is there documentation through publications, conferences, etc. that demonstrates progress, accomplishments, and collaboration? Is there evidence that the registry has met its objectives and been well utilized by the WTC Health Program and

external researchers? Is there adequate justification for adding new projects or cores or for deleting components previously supported? Is there evidence of transfer of research findings? Have the specific commitments and plans for the Registry from the previous project period been met? Have high quality outputs contributed to improvements relevant to the WTCHP or broader occupational or public health practices?

Additional Review Criteria
As applicable for the project proposed, *reviewers will evaluate* the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but *will not give separate scores* for these items.

Protections for Human Subjects
For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements (http://www.cdc.gov/od/pgo/funding/grants/additional_req. shtm#ar1).

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (http://www.cdc.gov/OD/foia/policies/inclusio.htm).

Vertebrate Animals
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and

tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards
Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Additional Review Considerations
As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact/priority score.

Applications from Foreign Organizations
Not Applicable.

Resource Sharing Plans
HHS/CDC policy requires that recipients of grant awards make unique research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: http://www.cdc.gov/od/foia/policies/sharing.htm. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Program staff will be responsible for the administrative review of the plan for sharing research resources and data. The adequacy of the resources sharing plan will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (HHS/PHS 2590; http://grants.nih.gov/grants/funding/2590/2590.htm). See Section VI. 3. Reporting.

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC/NIOSH peer review policy and procedures, using the stated review criteria.
As part of the scientific peer review, all applications will:

- be discussed and assigned an overall impact/priority score
- receive a written critique

Applications will compete for available funds with all other recommended applications submitted in response to this FOA.

Following initial peer review, recommended applications will receive a second level of review for programmatic relevance. The following will be considered in making funding decisions:

- Scientific and technical merit as determined by scientific peer review.
- Availability of funds.
- Relevance to WTCHP priorities.
- Comprehensive nature of the proposed registry.
- Commitment of the applicant institution to collaborative efforts.
- Nature and extent of coordination or collaboration with other WTCHP components.
- Administrative/managerial capability of the applicant institution.

3. Anticipated Announcement and Award Dates

After the peer review of the application is complete, the PD/PI will be able to access his or her Summary Statement (written critique) via eRA Commons.

Information regarding the disposition of applications is available in the HHS Grants Policy Statement (http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html).

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this FOA will be subject to the DUNS, CCR Registration, and Transparency Act requirements. If the application is under consideration for funding, NIOSH will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html) and in the NIH Grants Policy Statement.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV. 5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

2. Administrative and National Policy Requirements

All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award (http://dhhs.gov/asfr/ogapa/grantinformation/hhsgps107.pdf).

Additional requirements are available at the following internet address: http://www.cdc.gov/od/pgo/funding/Addtl_Reqmnts.htm.

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U. S. Office of Management and Budget (OMB) administrative guidelines, U. S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and CDC grant administration policies.

Cooperative Agreement Terms and Conditions
The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

Principal Investigator (PI) Rights and Responsibilities
The PD(s)/PI(s) will have primary responsibility for:

- Outreach - Planning and implementing strategies and approaches that will sustain general interest and knowledge about the WTC Registry to enhance continued participation. Utilizing existing contacts with business and community groups and organizations to facilitate outreach.
- Public Information Responsiveness – Supporting and maintaining a system for receiving and answering calls from the public regarding concerns, and questions on the WTC Registry (NYCDOHMH call center). Creating and maintaining a web site for the provision of easily accessible and up-to-date information about the WTC Registry.
- Database and Analysis Infrastructure - Certifying that data are prepared for analysis within defined, optimal time frames. Developing mechanisms for sharing selected and appropriate data elements with other WTC-related organizations that are also serving people who are impacted by their exposure to hazards associated with the WTC experience. Verifying protocols for protecting the database from security violations and confidentiality breaches. Verifying protocols for database backup and recovery.
- Update information on WTC registrants – Establishing an infrastructure for regularly contacting WTC Registrants. Sending letters requesting updated contact information to a large proportion of registrants, selected based on exposure category. Managing staff and data system for inputting and correcting registrant contact information.
- Data dissemination – Preparing regular reports on enumeration of registrant populations, descriptive summaries, and emerging patterns of exposure or health status.
- Registry Follow-Up Survey – to assess the basis for continuing the prospective analysis of the long-term health effects of the exposures associated with the WTC attacks and the aftermath.
- Health Status Surveys –Matching registrants with cancer registries, hospitalization data, and vital records. Performing appropriate analysis and disseminate findings.

- External registry studies - Establishing methods and processes for permitting other researchers to use the registry. Setting up a system for other bona fide researchers to obtain, under a formal request, de-identified registry data. Setting up and managing a process for contacting consented registrants about other studies in which they may enroll.
- Program Evaluation - Conducting an assessment of (1) the relevance of the program's activities to improving the health status of the cohort and (2) the impact that the program has had in reducing illness. Measures of contribution should include outputs of the program and outcomes (intermediate or final) that are attributable to the program's activities. Quantitative measures should be included and explained.
- Consultation and Collaboration - Developing science based capacity for conducting epidemiological and demographic research related to the Registry under separate funding.
- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.

HHS/CDC/NIOSH Responsibilities
CDC/NIOSH staff will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- Developing and maintaining the infrastructure for managing and conducting outreach activities.
- Developing information to be given to the public regarding concerns and questions on the WTC Registry, as well as communication materials that will inform and encourage enrollees to continue their participation.
- Evaluating registry information and data that describe the status of the cohort on a regular basis.
- Consulting on the survey to evaluate prospectively the long-term health effects in this cohort associated with the WTC attacks.
- Consulting on health status surveys for selected samples of registrants.
- Consulting on the evaluation plans for the Registry to determine its relevance to the improvement of health for the cohort and measures of impact.
- Developing a system that will permit other researchers to use the registry data.

Additionally, an agency program official or CIO program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

3. Reporting
Federal Funding Accountability and Transparency Act of 2006: Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible Web site, http://www.usaspending.gov/.

The web site includes information on each Federal financial assistance award and contract over $25,000, including such information as:

1. The name of the entity receiving the award
2. The amount of the award
3. Information on the award including transaction type, funding agency, etc.
4. The location of the entity receiving the award
5. A unique identifier of the entity receiving the award; and
6. Names and compensation of highly-compensated officers (as applicable)

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: 1) information on executive compensation when not already reported through the Central Contractor Registry; and 2) similar information on all sub-awards/subcontracts/consortiums over $25,000.

For the full text of the requirements under the Federal Funding Accountability and Transparency Act of 2006, please review the following website: http://frwebgate. access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:s2590enr.txt.pdf.

When multiple years are involved, awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11160) annually and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required when for closeout an award is relinquished, as described in the HHS Grants Policy Statement.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)

Contact Center Phone: 800-518-4726
Email: support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U. S. Eastern Time

Scientific/Research Contact
Travis Kubale, Ph.D.
CDC/NIOSH/OEP
1600 Clifton Road NE, Mailstop E74
Atlanta, GA 30329-4018
Telephone: 513-841-4461
Fax: 404-498-2571
TKubale@cdc.gov

Peer Review Contact
George Bockosh
CDC/NIOSH/OEP
1600 Clifton Road NE, Mailstop E74
Atlanta, GA 30329-4018
Telephone: 412-352-5181
Email: GBockosh@cdc.gov

Financial/Grants Management Contact
Ruben Cruz
CDC Procurement and Grants Office, Field Branch V
626 Cochrans Mill Road
P. O. Box 18070
Pittsburgh, PA 15236-0070
Telephone: (412) 386-6724
Fax: (412) 386-6429
Email: RCruz@cdc.gov

Section VIII. Other Information

All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations
Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations. Awards are made under the authorization of the Occupational Safety and Health Act of 1970, Section 20(a) and 21(a) (29 USC 669(a) and 29 USC 670); Federal Mine Safety and Health Act, Section 501(a), 30 USC 951(a); the James Zadroga 9/11 Health and Compensation Act of 2010 (Public Law 111-347; 42 USC 300mm – 300mm-61); Section 301 of the Public Health Service Act as amended (42 USC 241) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.